

Mannitol inhalations as faster procedure for testing of airways hyperresponsiveness.

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Measurement of airways hyperresponsiveness by mannitol (Aridol®) as compared to methacholine saves time to the lung function technician, while being as sensitive to discern hyperresponsive from normo-responsive, and being at least equally acceptable...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21125

Bron

NTR

Verkorte titel

N/A

Aandoening

Asthma, COPD, subjects without airways hyperresponsiveness

Ondersteuning

Primaire sponsor: Department of Respiratory Medicine

University Medical Center Groningen

Postbox 30.001

9700RB Groningen

the Netherlands

Overige ondersteuning: Pharmaxis Ltd.

2/10 Rodborough Rd, Frenchs Forest NSW 2086

Australia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time involved in measurement of hyperresponsiveness (including technician time for preparation and cleaning).

Toelichting onderzoek

Achtergrond van het onderzoek

Airway hyperresponsiveness (AHR) can be measured with direct (histamine or methacholine) and indirect agents (AMP, hypertonic saline, exercise and mannitol). We believe that measurement of airways hyperresponsiveness by mannitol (Aridol©) as compared to methacholine saves time to the lung function technician, while being as sensitive to discern hyperresponsive from normo-responsive. We will assess the saved time in this randomised, single-blinded, cross-over study.

Doel van het onderzoek

Measurement of airways hyperresponsiveness by mannitol (Aridol©) as compared to methacholine saves time to the lung function technician, while being as sensitive to discern hyperresponsive from normo-responsive, and being at least equally acceptable to patients presenting at a pulmonary out-patient clinic.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Measurement of bronchial hyperresponsiveness with mannitol and methacholine.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Asthmatics:

1. Episodic symptoms of dyspnea, and/or wheezing, and/or cough.
2. Allergic or non-allergic.
3. non current smokers (> 0.5 years).
4. PC20 MCh < 8 mg/ml

COPD patients:

1. Age > 40 yrs.
2. Active or former smokers, with a smoking history of more than 10 packyears.

3. Continuous symptoms of cough/sputum and/or dyspnea on exertion.
4. No history of asthma.
5. FEV1/FVC < 70 % and FEV1 between 50 and 80 % pred.

Controls:

1. No history of asthma or COPD;
2. PC20 MCh > 8 mg/ml;
3. FEV1/FVC > 70 % and FEV1 > 90 %pred.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years.
2. Inability to perform acceptable-quality spirometry or to understand directions given by personnel.
3. Severe airflow limitation (FEV1 < 50% of predicted or < 1.0 L).
4. Heart attack or stroke in last 3 months.
5. Uncontrolled hypertension, systolic BP > 200, or diastolic BP > 100.
6. Known aortic aneurysm.
7. Pregnancy.
8. Nursing mothers.
9. Current use of cholinesterase inhibitor medication (for myasthenia gravis).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	29-08-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL746
NTR-old	NTR756
Ander register	: Griac001
ISRCTN	ISRCTN72604310

Resultaten

Samenvatting resultaten

Planned